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ATTORNEY'S DOCKET NUMBER TRANSMITTAL LETTER TO THE UNITED STATES 96700/1031 DESIGNATED/ELECTED OFFICE (DO/EO/US) **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** INTERNATIONAL FILING DATE

PPLICATION NO. (If known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO. PCT/US2004/001773 January 23, 2004 Januarv 24. 2003 TITLE OF INVENTION USE OF MYCOBACTERIAL VACCINES IN CD4+ OR CD8+ LYMPHOCYTE-DEFICIENT MAMMALS APPLICANT(S) FOR DO/EO/US William R. Jacobs, Jr.; Tsungda Hsu; Stoyan Bardarov; Vasan Sambandamurthy; Sheldon Morris Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9 An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12 An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. 15 A substitute specification. 16. A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18 A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mall Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

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PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
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U.S. APPLICATION	10 15 4	2958	PCT/US2004/0		96700/1031	KET NUMBER
20. Other items or information: cover letter and return receipt postcard (enclosed)						
The following fees have been submitted					CALCULATIONS	PTO USE ONLY
21. Basic national fee (37 CFR 1.492(a))					\$ 300	TIO OSE ONE!
22. Examination fee (37 CFR 1.492(c))						
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0 All other situations\$200					\$ 200	
23. Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority					\$ 100	
TOTAL OF 21, 22 and 23 =					600	
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.						
Total Sheets Extra Sheets Number of each additional 50 or fraction thereof (round up to a whole number)						
115 - 100 = 15 /50 =			1 x \$250		\$ 250	1
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).					\$	
CLAIMS NUMB		ER FILED	NUMBER EXTRA	RATE	\$	
Total claims		20 - 20 =	0	× \$ 50	\$	
Independent claims		2 -3=	0	× \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + ,\$360					\$	
TOTAL OF ABOVE CALCULATIONS =					\$ 850	
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.						
SUBTOTAL =					\$ 425	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).					\$	
TOTAL NATIONAL FEE =					\$425	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +					\$	
TOTAL FEES ENCLOSED =					\$ 425	
					Amount to be refunded:	\$
					Amount to be charged	\$

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. A check in the amount of \$ 425 to cover the above fees is enclosed. Please charge my Deposit Account No. in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 01-1785. A duplicate copy of this sheet is enclosed. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. i My SEND ALL CORRESPONDENCE TO: Craig J. Arnold, Esq. Amster, Rothstein & Ebenstein LLP Elie H. Gendloff 90 Park Avenue NAME New York, NY 10016 44,704 REGISTRATION NUMBER "Express Mail" mailing label No. EL 996373289 US Date of Deposit: July 21, 2005 I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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July 21, 2005

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Signature: | Lie | Lie

Re: United States National Stage Filing

of PCT Application PCT/US2004/001773

Title:

USE OF MYCOBACTERIAL VACCINES IN CD4+ OR

CD8⁺ LYMPHOCYTE-DEFICIENT MAMMALS

Applicants: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardarov,

Vasan Sambandamurthy and Sheldon Morris

Our File: 96700/1031

Sir:

Pursuant to 35 U.S.C. § 371 and 37 C.F.R. § 1.495, enclosed please find an application for patent in the names of William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardarov, Vasan Sambandamurthy and Sheldon Morris, entitled "USE OF MYCOBACTERIAL VACCINES IN CD4⁺ OR CD8⁺ LYMPHOCYTE-DEFICIENT MAMMALS," for entering the national stage in the United States of America, comprising the following:

- 1. a "Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Submission Under 35 U.S.C. § 371," Form PTO-1390 (3 pages);
- 2. a copy of PCT Application No. PCT/US2004/001773 as published under PCT Publication No. WO 2004/066928 A2, including cover page (1 page), specification (82 pages), claims (6 pages), figures (27 sheets);

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July 21, 2005

- 3. a Preliminary Amendment (5 pages);
- 4. an AR&E check in the amount of \$425 to cover the total filing fees; and
- 5. a return receipt postcard.

Please charge any outstanding amount or credit any overpayment to Deposit Account No. 01-1785. A duplicate copy of this letter is enclosed.

Please also acknowledge receipt of the enclosed documents by stamping the enclosed postcard and returning the same to us.

Respectfully submitted,

Amster, Rothstein & Ebenstein LLP Attorneys for Applicants 90 Park Avenue New York, NY 10016 212 336 8000

Dated: New York, New York

July 21, 2005

Elie Gendloff

Registration No. 44,704